

CBI MARKET SURVEY

THE PHARMACEUTICAL PRODUCTS MARKET IN ITALY

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Report summary

This CBI market survey discusses the following highlights for the pharmaceutical products market in Italy:

- Italy was the third largest pharmaceutical market in the EU in 2007, accounting for 12% of total EU consumption. Between 2003 and 2007, Italy's consumption of pharmaceutical products increased by an annual average rate of 3.5%, amounting to € 16.7 billion in 2007.
- In 2007, Italy was the third largest market for generic medicines in the EU, amounting to € 3.4 billion, which accounted for 12% of the total EU market.
- In 2007, Italy was the fourth largest producer of pharmaceutical products in the EU, accounting for 14% of total EU production. Italy's production increased by an annual average rate of 5.7% between 2003 and 2007, amounting to € 22.5 billion in 2007.
- In 2008, Italy was the fifth largest importer of pharmaceutical products in the EU, accounting for 7.2% of total EU imports. Between 2004 and 2008, Italy's imports increased by an annual average rate of 7.0% in value and 9.3% in volume, amounting to € 7.9 billion or 87 thousand tonnes in 2008.
- Imports of pharmaceutical products sourced in developing countries accounted for a negligible share of 0.1% of total Italian imports in 2008. Nonetheless, these imports increased by a strong annual average rate of 59% between 2004 and 2008.

This survey provides exporters of pharmaceutical products with sector-specific market information related to gaining access to Italy. By focusing on a specific country, this survey provides additional information, complementary to the more general information and data provided in the CBI market survey 'The pharmaceutical products market in the EU', which covers the EU market in general. That survey also contains an overview and explanation of the selected products dealt with, some general remarks on the statistics used, as well as information on other available documents for this sector. It can be downloaded from <http://www.cbi.eu/marketinfo>

1 Market description: consumption and production

Data concerning consumption and production of pharmaceutical products in Italy are derived from the European Federation of Pharmaceutical Industries and Associations (EFPIA). The latest report from this organisation (The Pharmaceutical Industry in Figures, 2009 Update) provides data as of 2007. Data for previous years are derived from previous editions of this report. Please note that data for both consumption and production of pharmaceutical products are given at ex-factory prices.

Consumption

Italy was the third largest pharmaceutical market in the EU in 2007, accounting for 12% of total EU consumption. France, the largest – together with Germany - pharmaceutical market in the EU, individually accounted for approximately 18% of the EU pharmaceutical market in 2007. Between 2003 and 2007, Italy's consumption of pharmaceutical products increased by an annual average rate of 3.5%, amounting to € 16.7 billion in 2007 (EFPIA, 2009). Italy's pharmaceutical consumption increased at a slightly lower rate than the average EU consumption of pharmaceuticals, which grew by an annual average rate of 7.3% in the review period.

Please, note that data on consumption of specific pharmaceutical products are fragmented and cannot be presented in a structured manner. Additional information can be found under the section 'Trends in consumption'.

Generic medicines

In 2007, Italy was the third largest market for generic medicines in the EU, amounting to € 3.4 billion, which accounted for 12% of the total EU market. Between 2005 and 2007, the market for generic medicines in Italy increased at a rate of 28%. Generic medicines in Italy accounted for 20% of this market in 2007, which was around the EU average. In Germany, the largest generic medicines market in the EU, the value share of generics was 30% in the same year.

According to Pharmaceutical Pricing and Reimbursement Information (PPRI, 2007), the generic medicines sector in Italy is still small in comparison to other European countries. The existence of a market of copies (pharmaceutical products with the same active substance and packs marketed with their own brand name), as well as easy extension of patent coverage, poses barriers to the development of the Italian generic medicines market. In addition, the reference pricing in Italy is set at the level of the cheapest generic medicine, which inhibits the entry of generic medicines in the market. Moreover, Italian physicians have few incentives to prescribe generics, and pharmacists are financially penalized for dispensing generic medicines.

In fact, generic medicines were only introduced in Italy in 1996, although the main policy measures to promote the generic pharmaceuticals market were launched first in 2000. This included the reference pricing (RP) scheme, under which patients pay part of the cost of high-priced products (patient co-payment); the pharmacists' right of substitution; and a promotional and informational campaign to patients, in order to increase their generic-friendly awareness (PPRI, 2007).

Market segmentation

The Italian pharmaceutical market can be segmented in two distinct – but interlinked – manners: the dispensing method and the channels through which pharmaceutical products are dispensed to patients.

Regarding the **dispensing method**, the Italian market for pharmaceuticals consisted for 89% of prescription products, whereas 11% was non-prescription products in 2008. The **channels** through which pharmaceutical products are dispensed to patients are divided into two categories: general access pharmacies and hospital pharmacies. Other retail channels remain limited, as indicated below:

- *General access pharmacies:* these pharmacies consist of a retail storefront, in which there is a dispensary where pharmaceutical products are stored and dispensed. The dispensary is subject to the pharmaceutical legislation, which has specific requirements for storage conditions, handling equipment, warnings, etc. Pharmacies are by far the leading segment in the distribution of pharmaceutical products in Italy. Nonetheless, this monopoly is under threat, because supermarkets and other non-pharmaceutical channels have recently been allowed to sell non-prescription pharmaceutical products (PPRI, 2007).
- *Hospital pharmacies:* they usually handle more complex pharmaceutical products, with specific indications which require stricter safety regulations and patient compliance. Most of the products in these pharmacies are single-dose or unit dose. Hospital pharmacies are usually located in the premises of hospitals, with trained personnel, quality assurance and adequate facilities. In some countries, hospital pharmacies are used only for inpatient treatment and the products channelled through hospital pharmacies in those countries are not available for outpatients. In Italy, hospitals are allowed to dispense pharmaceutical products to both inpatients and outpatients.
- *Other retail channels:* Since August 2006, non-prescription pharmaceutical products have been sold through channels other than pharmacies in Italy, although only authorised if the products are dispensed under the supervision of a qualified pharmacist (Espicom, 2008). Furthermore, the distance-selling of non-prescription medicines is not allowed in Italy (Association of European Self-Medication Industry - AESGP, 2009).

According to EFPIA (2008), the shares of each segment of pharmaceutical sales in Italy amounted to approximately:

- Pharmacies (general access): 72%
- Hospital pharmacies: 8%
- Other retail channels: 0%

Trends in consumption

- **Cost containment and generic medicines:** Due to cost-containment policies in the health care sector adopted by the Italian government as of 2007, a significant increase in the use of generic medicines increased during 2008 in the country. Some Italians still regard generic medicines as inferior to branded pharmaceutical products. Thus, an information campaign was launched by the Italian Pharmaceutical Agency in 2007 to promote the use of this group of pharmaceutical products (Global Insight, 2008).
- **Top-selling prescription products (by therapeutic class):** The therapeutic classes in the group of prescription products which achieved the largest sales in 2008 were: central nervous system (29% of total sales), genital-urinary system (19%) and dermatological products (9%) (Farmindustria, Associazione delle imprese del farmaco, 2009).
- **Top-selling non-prescription products (by therapeutic class):** The therapeutic classes in the group of non-prescription products which achieved the largest sales in 2008 were: cough, flu and respiratory system (34% of total sales), digestive/ intestinal system (22%) and analgesics (19%) (Farmindustria, Associazione delle imprese del farmaco, 2009).
- **National Health Plan and research:** Following the elaboration of Italy's National Health Plan, which focuses on priority disease areas, more than 250 research projects have been approved (at a value of € 60 million, as of 2007). These research projects aim at industrial application, which results in the involvement of various pharmaceutical and biotech companies in the country. The priorities research areas are: cardiovascular diseases, oncology, infectious diseases, neurodegenerative conditions, immune system disorders and molecular medicine and genetic diseases (Dr Fiz Kermani: 'Italy's Pharmaceutical Renaissance', 2007).

For more information on pharmaceutical products trends, please refer to the CBI survey 'The pharmaceutical products market in the EU'.

Production

In 2007, Italy was the fourth largest producer of pharmaceutical products in the EU, accounting for 14% of total EU production. France, the largest EU producer, accounted for 21% of total EU production. Italy's production increased by an annual average rate of 5.7% between 2003 and 2007, amounting to € 22.5 billion in 2007. The increase in Italy's production was higher than the average increase in the EU production, which grew at an annual average rate of 3.5% during the review period.

In 2006, there were 243 registered pharmaceutical producers in Italy, employing 74,627 people (Piribo, 2007). In addition, there were 61 companies specialising in generic medicines in 2005, and they were members of the 'AssoGenerici' association (PPRI, 2007).

Most major international pharmaceutical companies such as Roche, Glaxo Smith Kline, Pfizer, Sandoz and Bayer have a strong presence in Italy, controlling about 60 to 65% of the total pharmaceutical market. In addition to these large multinationals, the leading pharmaceutical companies in Italy are:

- Angelini – <http://www.angelini.it>
- Chiesi – <http://www.chiesigroup.com>
- Menarini – <http://www.menarini.com>
- Recordati – <http://www.recordati.it>
- Rottapharm – <http://www.rottapharm.com>
- Sigma-Tau – <http://www.sigmatau.com>
- Zambon – <http://www.zamboncompany.com>

The companies which dominate the generic medicines market in Italy are large multinationals, such as:

- Teva – <http://www.tevapharm.com> - one of the world's leading pharmaceutical companies; its home-base country is Israel
- Ratiopharm – <http://www.ratiopharm.com> - Europe's leading generic company; German-based
- Merck KGaA – <http://www.merck.de> - German-based pharmaceutical and chemical company

All these are subsidiaries of overseas companies. The sector has continued to consolidate, which results in a smaller number of large companies dominating the market.

Please note that data concerning the production of specific product groups in Italy are not available.

In addition to its production, Italy's pharmaceutical industry Research and Development in 2007 was estimated at € 1.2 billion, accounting for approximately 5.2% of total EU pharmaceutical industry R&D. The UK, which had the leading pharmaceutical industry R&D, accounted for a share of 29% of total EU R&D.

Trends in production

- **Crisis in the pharmaceutical sector:** Influenced by the global economic crisis, the pharmaceutical industry in Italy is facing a major crisis. Several foreign-owned pharmaceutical multinationals in Italy, such as AstraZeneca, Wyeth and Merck, have announced job cuts. The closing of the *Istituto di Ricerca di Biologia Molecolare (IRBM) P. Angeletti*, resulting in the further dismissal of hundreds of employees, also affects Italy's research and innovation capacity (Eurofound, 2009).

For more information on pharmaceutical products trends, please refer to the CBI survey 'The pharmaceutical products market in the EU'.

Opportunities and threats

- + Italy is one of the largest EU markets for pharmaceutical products, and its market is increasing at a stable rate. Italy's ageing population and the increasing consumption of non-prescription pharmaceutical products have a major influence on this growth.
- + Although limited and full of obstacles, Italy is also increasing in importance as a market for generic medicines. In fact, the Italian generic medicines market is increasing at constant rates, which provides good prospects for exporters of pharmaceutical products in developing countries.
- At the same time, however, Italy is a strong producer of pharmaceutical products, which might be a restrictive factor for potential suppliers to this market. Moreover, its production of generic medicines is dominated by multinationals, which are strongly established in the Italian market.
- The strict regulations and requirements for the entry of pharmaceutical products into the EU might represent one of the greatest threats to the access of exporters in developing countries, specifically to the Italian market.

Exporters should take into account that the same trend can be an opportunity for one exporter and a threat to another. Please, review these opportunities and threats according to your own situation. Chapter 7 of the CBI market survey 'The pharmaceutical products market in the EU' presents an example of an analysis of whether a trend/development is an opportunity or a threat.

Useful sources

- Pharmaceutical Pricing and Reimbursement Information: Italy - http://ppri.oebig.at/Downloads/Results/Italy_PPRI_2007.pdf
- Italian Ministry of Health – <http://www.ministerosalute.it> (in the Italian language)

- The Business Monitor publication 'The Italy Republic Pharmaceuticals & Healthcare Report 2009' - <http://www.businessmonitor.com/pharma/italy.html> - provides forecasts on the Italian pharmaceutical and healthcare industry.
- Espicom - <http://www.espicom.com> - the pharmaceutical and medical device knowledge centre
- European Federation of Pharmaceutical Industries and Associations (EFPIA) - <http://www.efpia.org>
- Furthermore, Italian trade associations mentioned in Chapter 6 of this survey can be useful sources of information.

2 Trade channels for market entry

Trade channels

The trade structure for pharmaceutical products across the EU is mostly similar, but reveals slight variations according to the diverse pharmaceutical and healthcare systems existent in each country. These variations hardly affect an exporter's market approach, since they are related to the way pharmaceutical products are domestically dispensed to the end-consumer. Some of the specific characteristics of the Italian pharmaceutical trade channels and trends therein are outlined below:

- The distribution of pharmaceutical products in Italy has traditionally been fragmented; consolidation has started fairly recently. In 2007, 110 **wholesalers** were registered in the country. In France, for instance, only three wholesalers dominate the market, while in Italy a total of only six wholesalers is active (Associazione Distributori Farmaceutici (ADF), 2007).
- As mentioned previously, **non-prescription pharmaceutical products** have been sold through channels other than pharmacies in Italy since August 2006, although only authorised if the products are dispensed under the supervision of a qualified pharmacist (AESGP, 2009).
- Nonetheless, the Italian Senate still has to ratify a 2007 proposal concerning the sale of **non-reimbursable prescription pharmaceutical products** outside of pharmacies (PPRI, 2007).
- Neither **Internet pharmacies/e-commerce** nor sale of pharmaceutical products by e-mail or mail orders are allowed in Italy. **Doctors** are not allowed to dispense pharmaceutical products either (PPRI, 2007; AESGP, 2009).
- **Parallel trade** of pharmaceutical products does not represent a significant portion of the Italian pharmaceutical market. In fact, Italy plays a greater role as an exporter when it comes to parallel trade of pharmaceutical products (PPRI, 2007).

Please, refer to the CBI survey 'The pharmaceutical products market in the EU' for further information on EU pharmaceutical trade channels.

Players of interest to exporters in developing countries are:

- Combiphar (subsidiary of Phoenix) - <http://www.combiphar.com> - pharmaceutical wholesaler
- Alleanza Salute (subsidiary of Alliance Unichem) - <http://www.alliance-healthcare.it> - pharmaceutical wholesaler
- Farmintesta (subsidiary of Secof) - pharmaceutical wholesaler
- So Farma Morra - <http://www.sofarmamorra.it> - pharmaceutical wholesaler

For more possible interesting players, please refer to the website of Italian wholesalers association: <http://www.adfsalute.it>

Price structure

Pricing and reimbursement of pharmaceutical products in the EU are issues of national competence. Therefore, the EU consists of 27 different pricing and reimbursement systems.

In Italy, prices for reimbursable pharmaceutical products are centralised and applied equally throughout the country. Nonetheless, pharmaceutical products which are not reimbursed are under a system of free pricing. Prices of non-prescription products are modified by pharmacists, but this results in price fluctuations across the country, which might even exceed the official maximum prices.

In relation to the reimbursable pharmaceutical products, it is the Italian Medicines Agency (AIFA) which is in charge of pricing for products of different strengths and dosage. Along with the Committee for Pricing and Reimbursement (CPR), AIFA negotiates pharmaceutical product prices with pharmaceutical companies. In this sense, prices are decided at the ex-factory level. Subsequently, the wholesale and pharmacy prices are calculated by formula.

Different prices apply throughout the various trade channels. The margins applied to pharmaceutical products in Italy can be expressed in the following manner:

- Manufacturer: 66.6% (for reimbursable pharmaceutical products)
- Wholesaler: 6.6% (for reimbursable pharmaceutical products)
- Pharmacist: 26.7% (for reimbursable pharmaceutical products)
- State (Value Added Tax - VAT): a discounted VAT of 10% is applicable to pharmaceutical products (the standard VAT rate is 20%)

The margin for the non-reimbursable market segment is free and is not regulated by law.

Generic medicines

In general, the procedure for the pricing of generic medicines does not differ from the general pricing methods and procedures for original pharmaceutical products. By law, however, the price of a generic medicine in Italy should be set at minimum 20% below the price of the comparable originator product.

For further information on price structure of pharmaceutical products in Italy, please refer to: http://ppri.oebig.at/Downloads/Results/Italy_PPRI_2007.pdf

Selecting a suitable trading partner

Finding a trade partner in Italy does not deviate from the general EU method as described in the EU export guidelines. Italian importers look for new suppliers in developing countries by visiting the country of interest, through recommendations or through trade fairs. The most common ways for developing country exporters to approach Italian customers are through direct (e)mail, personal visits as follow-up, inviting potential Italian customers to visit them, building a network and visiting international trade fairs.

After obtaining contacts, evaluating potential trade partners should be done according to criteria such as information quality, geographic coverage; the kind of trade relation the partner is interested in, the position of the partner and the financial status and credibility.

The following websites can be of use when finding a trading partner in Italy:

- Europe Bloombiz.com - <http://europe.bloombiz.com> → Click on 'companies' in the centre of the page, and then search for 'pharmaceutical products', and select Italy in the country-list.
- Europages - <http://www.europages.com> - online business directory, with full EU coverage. Search for 'pharmaceutical products' and filter by country, selecting Italy on the left-sided tab 'Refine your search'.
- PharmaBuyers.com - <http://www.pharmabuyers.com> - provides contact information of 580 European importers of pharmaceutical products at a cost of US\$40 (updated in 2009).

3 Trade: imports and exports

Imports

Total imports

In 2008, Italy was the fifth largest importer of pharmaceutical products in the EU, accounting for 7.2% of total EU imports. Between 2004 and 2008, Italy's imports increased by an annual average rate of 7.0% in value and 9.3% in volume, amounting to € 7.9 billion or 87 thousand tonnes in 2008. Nearly 80% of total Italian imports of pharmaceutical products in 2008 was sourced in intra-EU countries. Belgium, France and Germany were the leading EU suppliers, accounting for respective shares of 15%, 14% and 12% of total Italian imports. Between 2004 and 2008, imports sourced in intra-EU countries increased by an annual average rate of 8.2% in terms of value. Imports sourced in extra-EU countries (excluding DCs) accounted for 21% of total Italian imports in 2008, and increased at an annual average rate of 2.9% in the review period.

Imports sourced in developing countries accounted for a negligible share of 0.1% of total Italian imports in 2008. Nonetheless, these imports increased by a strong annual average rate of 59% between 2004 and 2008.

In 2008, total Italian imports of pharmaceutical products consisted of packed pharmaceutical products (96%) and non-packed pharmaceutical products (4%).

**Table 3.1 Imports by and leading suppliers to Italy
2004 - 2008, share in % of value**

Product	2004 € mln	2006 € mln	2008 € mln	Leading suppliers in 2008 Share in %	Share (%)
Total pharmaceutical products	4,532	5,621	6,214	Intra-EU: Belgium (15%), France (14%), Germany (12%), Netherlands (12%), UK (8.6%)	79%
	1,503	1,612	1,683	Extra-EU ex. DC*: Switzerland (11%), USA (7.5%)	21%
	1.7	5.8	11	DC*: -	0.1%
Packed pharmaceutical products	4,281	5,458	6,014	Intra-EU: Belgium (15%), France (13%), Germany (12%), Netherlands (12%), UK (8.8%)	79%
	1,408	1,509	1,587	Extra-EU ex. DC*: Switzerland (12%), USA (7.4%), Japan (0.9%)	21%
	1.2	3.0	8.7	DC*: -	0.1%
Non-packed pharmaceutical products	250	163	200	Intra-EU: Ireland (22%), France (15%), Sweden (11%), Germany (10%), Belgium (4.9%)	67%
	94	103	95	Extra-EU ex. DC*: Japan (14%), USA (10%), Switzerland (6.1%)	32%
	0.5	2.8	2.4	DC*: Brazil (0.6%), India (0.1%), China (0.1%)	0.8%

Source: Eurostat (2009)

*Developing Countries

Imports by product group

Eurostat data were used for this section. However, as Eurostat classifies data on pharmaceutical products by non-packed products and packed products, a specific product selection cannot be made. For more information on the classification of non-packed pharmaceutical products and packed pharmaceutical products, please refer to Appendix A of the survey covering the EU.

Packed pharmaceutical products

In 2008, Italy was the fifth largest importer of packed pharmaceutical products in the EU, accounting for a share of 7.6% of total EU imports. Between 2004 and 2008, Italian imports increased by an annual average rate of 7.5% in value and 10% in volume, amounting to € 7.6 billion or 85 thousand tonnes in 2008.

Since imports of packed pharmaceutical products accounted for nearly the entirety of Italy's imports of pharmaceutical products in 2008, the developments for this product group were the same as the development for the overall group of pharmaceutical products.

Non-packed pharmaceutical products

In 2008, Italy was the third largest importer of non-packed pharmaceutical products in the EU, accounting for a share of 3.1% of total EU imports. Between 2004 and 2008, Italian imports decreased by an annual average rate of 3.7% in value and 6.9% in volume, amounting to € 297 million or 2.6 thousand tonnes in 2008.

Imports sourced in intra-EU countries accounted for 67% of total Italian supplies, of which Ireland was the leading supplier, with a market share of 22%. France, the second most important supplier, accounted for a market share of 15%. Other important suppliers in the EU were Sweden (11%), Germany (8.1%) and Belgium (4.9%). Italian intra-EU imports of non-packed pharmaceutical products decreased by an annual average rate of 5.5% in the review period.

Imports from extra-EU countries (excluding DCs) accounted for 32% of total Italian imports, of which Japan was the leading supplier, accounting for a 14% market share. USA (10%) and Switzerland (6.1%) were other important extra-EU (excl. DCs) suppliers. Extra-EU imports remained stable in the review period.

Imports from developing countries accounted for a slight share of 0.8% of total Italian imports of non-packed pharmaceutical products in 2008. In spite of accounting for a small share, Italian imports sourced in DCs increased by a strong annual average rate of 50% between 2004 and 2008. The leading DC suppliers in were Brazil (0.6%), India (0.1%) and China (0.1%).

Exports

In 2008, Italy was the sixth largest EU exporter of pharmaceutical products, accounting for a 6.1% share of total EU exports. Between 2004 and 2008, Italian exports increased by an annual average rate of 6.0% in value and 6.5% in volume, amounting to € 8.1 billion or 183 thousand tonnes in 2008.

Approximately 64% of Italy's pharmaceutical products exports in 2008 was destined to EU countries, the main destination being Belgium, which received 20% of Italian exports. Germany, the second leading EU destination, accounted for a share of 10% of total Italian exports. Among extra-EU countries, Switzerland was the most popular destination for Italian exports, accounting for an export share of 13%. DCs accounted for 6.5% of total Italian exports.

In 2008, total Italian exports consisted of packed pharmaceutical products (98%) and non-packed pharmaceutical products (2%).

Opportunities and threats

- + Italy is one of the largest importers of pharmaceutical products in the EU and its imports experienced an increase in the review period, which indicates its potential for exporters in developing countries who aim at accessing the EU.
- In spite of importing substantial amounts of pharmaceutical products, Italy is a net exporter. In addition, the country does not import large proportions from developing countries. In 2008, Italian imports from DCs accounted for only 0.1% of total imports of pharmaceutical products.
- + Although imports from DCs account for a small share of total Italian imports, they experienced a strong annual average increase of 59% in the review period, which indicates that opportunities are being created for exporters in developing countries.
- + Imports of both packed and non-packed pharmaceutical products from developing countries had a positive development, which indicates that both product groups provide opportunities for developing country exporters.

- In spite of the increasing opportunities for developing countries in the Italian market for pharmaceutical products, the largest DC players are still countries such as India and China. This indicates that smaller players would face strong competition from DCs which already have an established position in the Italian and EU market.

Exporters should take into account that the same trend can be an opportunity for one exporter and a threat to another. Please, review these opportunities and threats according to your own situation. Chapter 7 of the CBI market survey 'The pharmaceutical products market in the EU' presents an example of an analysis of whether a trend/development is an opportunity or a threat.

Useful sources

- EU Expanding Exports Helpdesk
→ <http://exporthelp.europa.eu>
→ go to: trade statistics
- Eurostat – official statistical office of the EU
→ <http://epp.eurostat.ec.europa.eu>
→ go to 'themes' on the left side of the home page
→ go to 'external trade'
→ go to 'data – full view'
→ go to 'external trade - detailed data'
- Understanding Eurostat: quick guide to easy Comext
→
http://epp.eurostat.ec.europa.eu/newxtweb/assets/User_guide_Easy_Comext_20090513.pdf

4 Price developments

Pricing systems vary in the individual EU countries, thus this is also the case for price developments. The main price developments observed in Italy in the last few years are the following:

- In January 2006, reimbursed products, except haemo derivatives, recombinant DNA and vaccines, had their prices reduced by 4.4% at retail prices, including VAT and a 0.6% discount at manufacturers' prices.
- From mid July 2006, pharmaceutical products' price reductions at retail prices ranged from 4.4% to 5.0%, including VAT. Further price reductions of 5.0% were introduced in September 2006 and enforced in October 2006.
- From January 2008, the public price-setting of non-prescription medicines is totally free. The prices of these products are determined by the person responsible for the final sale. The VAT rate on pharmaceutical products remained 10%.

Useful sources

- ITC market news service (MNS) - <http://www.intracen.org>
- PPRI – Pharmaceutical Pricing and reimbursement Information - <http://ppri.oebig.at>

5 Market access requirements

As a manufacturer in a developing country preparing to access Italy, you should be aware of the market access requirements of your trading partners and the Italian government. Requirements are demanded through legislation and through labels, codes and management systems. These requirements are based on environmental, consumer health and safety and social concerns. You need to comply with EU legislation and have to be aware of the additional non-legislative requirements that your trading partners in the EU might request.

For information on legislative and non-legislative requirements, go to 'Search CBI database' at <http://www.cbi.eu/marketinfo>, select 'Pharmaceutical products' and 'Italy' in the category search, click on the search button and click on market access requirements.

Please refer to the CBI market survey 'The pharmaceutical products market in the EU' for information on the EU-wide legislation regulating imports, production and marketing of pharmaceutical products for human use, as well as information on packaging and labelling requirements.

Additional information on packaging can be found at the website of ITC on export packaging: <http://www.intracen.org/ep/packit.htm>

Information on tariffs and quota can be found at <http://exporthelp.europa.eu>

6 Doing business

General information on doing business like approaching potential business partners, building up a relationship, drawing up an offer, handling the contract (methods of payment, and terms of delivery) can be found in CBI's export manuals 'Export Planner' and 'Your image builder'. Furthermore, cultural awareness is a critical skill in securing success as an exporter. Information on cultural differences in the EU can be found in chapter 3 of CBI's export manual 'Exporting to the EU'. These manuals can be downloaded from <http://www.cbi.eu/marketinfo> - go to search publications.

In Chapter 2, the importance of networks, trade fairs and company visits was expressed in terms of promoting your company and finding trade partners. Trade fairs also offer useful information on trends, potential competitors and the products and services they offer. Trade press should not be underestimated, both as a source of information (i.e. trends, companies) and as a means of promoting your company and your products.

Trade associations

- Italian Pharmaceutical Association (AFI) - <http://www.afiscientifica.it> - aims to represent all professionals working in different areas of the pharmaceutical industry (website in Italian only)
- Farindustria, Associazione delle imprese del farmaco - <http://www.farindustria.it> (website in Italian only)
- National Association of Generic Medicines Industry (Assogenerici) - <http://www.assogenerici.org> (website in Italian only)
- Italian Medicines Agency (AIFA) - <http://www.agenziafarmaco.it> (website in Italian only)

Trade press

- Masson Elsevier - <http://www.masson.it>

Trade fairs

- Cosmofarma - <http://www.cosmofarma.com> - a leading trade fair in the pharmaceutical sector. The next event will take place in Rome, 7-9 May 2010.

This survey was compiled for CBI by ProFound – Advisers In Development
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